K052490

DEC 8 2005

# 510(k) Premarket Notification Summary

**Name/Address of Submitter**: Northern Implants, LLC
10355 B Democracy Lane
Fairfax, VA 22030

**Establishment Registration Number**: 3003845138

**Contact Person**: Greta M. Hols
Phone: (703) 278-3953
Fax: (703) 278-3954

**Date Summary Prepared**: Monday, August 29, 2005

**Device Classification Name**: Endosseous Implant and Accessories

**Device Classification Regulation Number:** 21 CFR 872.3640

**Device Regulatory Status:** Class II Special Controls

**Trade Name**: Endosseous Dental Implant

**Purpose:** The purpose of this 510(k) is to include additional implants and accessories in the NSI Hexed and Non-Hexed Endosseous Implant System that did not fall within the size range and design shapes identified in prior 510(k) submissions for our system.

**Performance Standards:** FDA has not established a performance standard applicable to endosseous implants and their accessories. The materials in the NSI Hexed Implant System meet applicable voluntary standards. Northern Implant's screw-type implants and abutments are manufactured from ASTM F67-95 Grade III or Grade IV Titanium.

**Predicate Devices**: K003620 NSI Hexed and Non-Hexed Implant System
K020617 NSI Hexed and Non-Hexed Implant System
K033171 NSI Hexed and Non-Hexed Implant System
K970499 Branemark System Zygomatic Implant
K894593 ITI Straumann's Angled Hollow Cylinder Implant

**Device Description and Intended Use**: The NSI Implant System is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses. It further adds the option for immediate placement and function on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

This implant is not intended, nor should it be used, in conjunction with an angled abutment.

**Technological Characteristics**: The physical properties and designs of the additional implants and accessories in the NSI Hexed and Non-Hexed Implant System were compared with legally marketed predicate devices. The technological characteristics were comparable.

**Brief Discussion of Clinical Studies**: Clinical studies were not conducted, or deemed necessary, for the purpose of this 510(k) submission.

**Brief Discussion of Engineering Studies**: Fatigue Testing was conducted per FDA Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental

Abutments that was issued on May 12, 2004. Modification to the testing protocol were discussed with the FDA prior to conducting the test (Enclosure 9). Testing revealed a stable screw joint at the highest forces tested (Enclosure 8). Finite Element Analysis was also conducted (Enclosure 10).

**Conclusions Drawn**: The NSI Hexed and Non-Hexed Implant System has the same intended use as, and technological characteristics similar to, the legally marketed predicate devices. Any differences in the technological characteristics did not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 8 2005

Ms. Greta M. Hols
Director
Northern Implants, LLC
10355 B Democracy Lane
Fairfax, Virginia 22030

Re: K052490
Trade/Device Name: Endosseous Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: August 29, 2005
Received: September 12, 2005

Dear Ms. Hols :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

# Indication for Use

510(k) Number:

Device Name: Endosseous Dental Implant System

Indication for Use: The NSI Implant System is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses. It further adds the option for immediate placement and function on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

This implant is not intended, nor should it be used, in conjunction with an angled abutment.

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## Concurrence of CDRH Office of Device Evaluation

Prescription Use ✓ OR Over-the-counter Use

(Per 21 CFR801.109)

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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